DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 24, 2014

Bio-Med USA Incorporated
Mr. Young Chi
President
27 New England Drive
Ramsey, New Jersey 07466

Re: K140837
Trade Name: LUCID LY
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 18, 2014
Received: August 22, 2014

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140837

Device Name
LUCID LY

Indications for Use *(Describe)*
LUCID LY, the laser system is indicated for: the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

1064nm Wavelength:
Tattoo removal: dark ink (black, blue and brown)
Removal of Nevus of Ota
Removal or lightening of unwanted hair with or without adjuvant preparation.
Treatment of Common Nevi, Melasma
Skin resurfacing procedures for the treatment of acne scars and wrinkle

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (K) Summary

As required by CFR 807.92(c)

1. Manufacturer.

Prepared Sept 18, 2014

BISON Medical Co., Ltd.
371-42 Gasan Dong,
Geum Cheon gu, Seoul 153-803, Rep of Korea
t: 82 2 865 7121, f: 82 2 865 7131

2. Submitter and Contact person

Bio-Med USA Inc.
Young Chi, President.
27 New England Drive, Ramsey, NJ 07446. U.S.A.
t: 1-973 278 5222 f: 1 201 934 6030
e mail: biomedusa@msn.com

3. Name of Device

Trade name	:	LUCID LY
Classification name :	:	Powered, Laser surgical instrument
Common name	:	Nd:YAG Surgical Laser
Regulation	:	878.4810 Class II
Classification Panel	:	General and Plastic Surgery.
Product Code	:	GEX

4. Legally marketed Predicate Device

K113588	Spectra	Nd:YAG	Lutronic Corp

Although, the predicate device has two wave length (1064nm, 532nm), and hand piece, other characteristics such as Design, Construction, Energy, Repetition rate, Cooling System, Intended use of wave length 1064nm are substantial equivalence to the proposed device.

5. Device Description

The LUCID LY , Nd:YAG laser system produces a one pulsed beam, 1064 nm Infrared light laser oscillation in tubes; power supplies, with non-contacted mode and consists of main function,

laser tube : placed in the mixed crystals of copper pipe to the heater and produces a laser beam,
Resonator : amplifies the beam, through the Xe-gas contained lamp
lamp : Xe-gas contains high pressure lamp to increase specific laser beam

This converted light energy creates the ND:YAG crystal and exhaust from the crystal is amplified into a specific wave length. Laser energy produced is delivered to the Tissue by means of an articulated arm and a specially designed multi spot Hand Piece.

The Physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam, and is able to activate laser emission using Foot Switch.

This system also consist of

Optic main Bench assembly, Fiber optic Hand pieces,
LCD control panel, Cooling system, Foot Pedal Switch

6. Performance test

Clinical and Non-Clinical performance test data was not provided in this submission.
But, manufactured in accordance with both mandatory and voluntary standard

IEC60601-1 part 1 : General requirement for basic safety and essential performance.
IEC60601-1-2: 2007 E M C test
IEC60601-2-22 Part 2, Particular requirements for safety of diagnostic and Therapeutic laser
IEC60825-1 :2nd ED, Equipment classification and requirement.

Lucid LY, demonstrates no significant different compare to the predicate device

7. Intended use

Lucid LY, the laser system is indicated for use to the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis,

1064nm wave length
Tattoo removal : dark ink (black, blue and brown)
Removal of Nevus of Ota,
Treatment of common Nevi, Melasma,
Removal or lightening of unwanted hair with our without adjuvant Preparation.
Skin resurfacing procedures for the treatment of acne scars and wrinkles.

8. Biocompatibility, Sterilization

This device are non-contacted mode.
Hand piece tips is made by same material as predicate device.

9.Conclusion.

LUCID LY, Nd: YAG laser system, in this submission, is substantially equivalent to several already cleared predicate device in respect to the Intended use, Main function, Technology, Principal operation and performance.
And every Safety test report show it as safe and effective as predicate device and it does not raise any additional issues for safety and effectiveness.

Bio-Med Inc will update and include in this summary any other information deemed seasonally necessary by the FDA

Comparison to Predicate Device

	Proposed Device	Predicate Device
Device	Lucid LY	Spectra / K113588
Manufacturer	Bison Medical Corp	Lutronic Corp
Laser type Wave	Nd:YAG	Nd:YAG
Length Beam	1064nm	1064nm /532nm
Profile Pulse	Top Hat Mode	Top Hat Mode
width	5-10ns	5-10ns
Fluence	up to 12 J/cm2	up to 12 j/cm2
Max Energy output	1.5j	1.5j
Max Pulse Energy	1000mj	1200mj
Spot size	1-8mm	1-8mm
Repetition /pulse rate	1,2,4,5,10Hz, single	1,2,4,5,10 Hz,signle
Pulse Duration Frequency	5-10ns	5-10ns
LCD	10.4" TFT LCD touch Closed	10.4"TFT LCD
Cooling	circuit water to air	circuit water to air
Dimension (wxdxh)	450x1040x950mm	295x656x1700mm
Input power	100-120va / 50-60Hz	100-120va / 50-60Hz
Temperature (c')	18-30'c	18-30'c
Relative humidity	30-75%	30-75%
Atmospheric Pressure	700-1060hPa	700-1060hPa
Weight Intended	122kg	88kg

Intended use

Lucid LY : This device is intended use for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis,

1064nm wave length

Tattoo removal : dark ink (black, blue and brown)

Removal of Nevus of Ota.

Treatment of common Nevi, Melasma,

Removal or lightening of unwanted Hair with or without adjuvant preparation,

Skin resurfacing procedures for the treatment of acne scars and wrinkle

Spectra / K113588: **Predicate Device**

This device is intended use for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis,

1064nm wave length

Tattoo removal : dark ink (black, blue and brown)

Removal of Nevus of Ota,

Treatment of common Nevi, Melasma,

Removal or lightening of unwanted hair with or without adjuvant preparation

Skin resurfacing procedures for the treatment of Acne Scars and Wrinkles

Comparison of Treatment parameter to predicate device

	Proposed device / K140837 Lucid LY	Predicate Device K113588 Spectra	
Indication for use	Spot size (mm)	Fluence (j/cm2)	# of Treatment
Tattoo Removal dark color (Black, Blue, Brown)	3 to 5 / 3 to 4	6.0 to 11.0 / 6.0 to 12.0	2 to 5 / 2 to 5
Acne Scares / Wrinkle	3 to 6 / 3 to 6	3.0 to 7.0 / 3.0 to 7.0	3 or more
Removal or lightening wanted hair with or without adjuvant preparation	6 / 7	2.0 to 3.0 / 2.5	1 / 1 or 2
Nevus of Ota	3 / 3	5.0 to 10.0 / 6.0 to 12.0	4 to 8 / 4 to 8
Melasma	6 / 8	1.0 to 2.0 / 1.0 to 1.5	6 to 8 / 8

As like above, relate Treatment Parameter is very similar to Predicate Device,